UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
ABINGDON DIVISION

UNITED STATES OF AMERICA v. COVETRUS NORTH AMERICA, LLC Defendant.	CRIMINAL No. 1:24-mj-00009-PMS

COVETRUS NORTH AMERICA, LLC'S MEMORANDUM IN AID OF SENTENCING

Covetrus North America, LLC ("Covetrus NA" or the "Company"), by and through counsel, submits this Memorandum in Aid of Sentencing in accordance with Federal Rule of Criminal Procedure 32(i)(1)(C) and in advance of the May 8, 2024, sentencing hearing. This case is one of three similar cases that have been presented to this Court involving the misbranding of veterinary drugs in violation of the federal Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. §§ 331(a), 333(a)(1), and 352(f)(1). *See United States v. Animal Health International, Inc.*, Crim. No. 1:20-cr-00007-JPJ-PMS and *United States v. Midwest Veterinary Supply, Inc.*, Crim. No. 1:23-MJ-00044-PMS. In both previous cases, the Defendant drug distributor pled guilty pursuant to Rule 11(c)(1)(C), paid significant, multi-million-dollar forfeitures, and agreed to make substantial legal compliance improvements. In both cases, this Court imposed a one-year term of probation.

A similar disposition is entirely warranted here. The parties have executed, and the Court has accepted, a guilty plea pursuant to Rule 11(c)(1)(C). (Plea Agreement, ECF No. 6; Redacted Plea Hearing Transcript, ECF No. 24 at 38:15-17). In accordance with the Plea Agreement, Covetrus NA has forfeited $21,534,091 and paid over $2,000,000 in fines and other assessments. The only outstanding sentencing issue is the term of probation, which the plea agreement limits to

"one to three years, as determined by the Court." (Plea Agreement, ECF No. 6 at 2). Given the substantial fines already paid, the Company's firm commitment to compliance efforts, and the goal of avoiding disparate sentences among similarly situated Defendants, Covetrus NA submits that a one-year term of probation is sufficient, but not greater than necessary, to satisfy the purposes of federal sentencing under 18 U.S.C. § 3553.

BACKGROUND

Defendant Covetrus North America, LLC is a distributor of veterinary drugs with its principal place of business in Dublin, Ohio. ECF No. 1 ¶ 1. Covetrus NA was previously known as Butler Animal Health Supply, LLC and was a subsidiary of Henry Schein, Inc. *Id.* In February 2019, Henry Schein spun off of its animal health business, including Butler Animal Health Supply, LLC and other animal health entities, which in turn merged with Vets First Choice to create Covetrus, Inc. *Id.* As part of the spin-merger, Butler Animal Health Supply, LLC became a subsidiary of Covetrus, Inc., and was re-named Covetrus North America LLC. Covetrus NA distributes veterinary drugs throughout the United States. The Company serves veterinarians administering to a variety of animals, but it primarily focuses on the companion animal market, not large animals in the human food supply chain.

As Covetrus NA has admitted in the Plea Agreement, between March 2019 and December 2021, Covetrus NA caused misbranded veterinary prescription drugs to be delivered in interstate commerce to various locations in the Commonwealth of Virginia and certain other states. *Id.* ¶ 7. In this context, misbranding entails the shipment of prescription drugs from wholesale distribution centers (as opposed to pharmacies) directly to end users (as opposed to veterinarians at a licensed location) in states that prohibit those shipments. *Id.* Covetrus NA sent these shipments as part of a program that was designed to increase efficiencies for veterinarians. Under the program, Covetrus

NA shipped veterinary drugs to locations, including farms, where veterinarians would administer them. As a result of this prosecution and others like it in this industry, Covetrus NA now understands that such shipments are unlawful in certain states, even when the veterinarian has established the requisite veterinarian-patient relationship. Covetrus NA has redesigned its business operations to comply with the FDCA, including creating a Large Animal Pharmacy and developing new compliance mechanisms in an effort geared toward the processing of lawful shipments.

On February 9, 2024, the Government filed an Information charging one Count of introducing misbranded drugs into interstate commerce in violation of 21 U.S.C. §§ 331(a), 333(a)(1), and 352(f)(1). The parties executed a Plea Agreement pursuant to Federal Rule of Criminal Procedure 11(c)(1)(C), under which Covetrus NA plead guilty to the single count Information and agreed to pay over $23 million in fines and forfeitures. The Company has made those payments. The Plea Agreement incorporates a Corporate Compliance Program Agreement ("CCA") which obligates Covetrus NA to undertake certain compliance measures designed to prevent violations of federal and state statutes and/or regulations concerning federal prescription drug distribution. These compliance measures include the appointment of a Compliance Officer, the formation of a Compliance Committee, and the implementation of programs and procedures designed to foster a culture of compliance and encourage employees to report suspected violations. The Corporate Compliance Program Agreement is operative for a period of forty-eight months. On February 12, 2024, this Court conducted a Plea Hearing and accepted the Plea, and agreed to impose the agreed-upon sentence.

COVETRUS NA'S SENTENCING POSITION

Any sentence imposed by this Court must be "sufficient, but not greater than necessary," to meet the purposes of federal sentencing as expressed in the Federal Sentencing Guidelines and

18 U.S.C. § 3553. *United States v. Hargrove*, 701 F.3d 156, 160 (4th Cir. 2012). To impose an appropriate term of probation, courts weigh the applicable sentencing factors enumerated at 18 U.S.C. § 3553(a). *See* 18 U.S.C. § 3562. These factors include the circumstances of the offense, the need for the sentence to reflect the seriousness of the offense and afford adequate deterrence, and the "need to avoid unwarranted sentence disparities among defendants with similar records who have been found guilty of similar conduct." 18 U.S.C. § 3553(a)(1), (2), and (6).

I. The Nature and Circumstances of the Offense Warrant a Term of Probation of One Year.

As set out in the Criminal Information, the FDCA prohibits misbranding of prescription drugs. Under the FDCA, a veterinary prescription drug is misbranded if it does not bear "adequate directions for use." 21 U.S.C. § 352(f)(1). Veterinary drugs are exempt from this requirement only if they are distributed through a closed supply chain in which every entity that possesses a prescription drug has legal authorization to do so. *See* 21 C.F.R. § 201.105. Moreover, all veterinary prescription drugs must be dispensed pursuant to a lawful order of a licensed veterinarian in the course of the veterinarian's professional practice. 21 U.S.C. § 353(f)(1) & 21 C.F.R. § 201.105(a)(2). The misbranding misdemeanor is a strict liability offense.

The Government has alleged, and Covetrus NA has admitted, that it misbranded veterinary drugs within the meaning of the FDCA by distributing drugs from its wholesale distribution locations to users or locations that were not authorized to receive those drugs under applicable state laws. State regulations governing the distribution of veterinary drugs vary from state to state. While all states require veterinary drugs to be dispensed only upon the issuance of a prescription, the states do not have uniform regulations governing the location to which drugs may be shipped from distribution centers. Some states, for example, require wholesale distributors (as opposed to pharmacies) to deliver drugs only to licensed veterinary facilities. While Covetrus NA had due

diligence processes to ensure that its customers were licensed veterinarians who had issued lawful prescriptions, it did not take sufficient steps to ensure that its prescription drugs were shipped to locations permissible under the laws of certain states. In shipping drugs directly to unlicensed end users, Covetrus NA violated certain state laws and, accordingly, misbranded veterinary medicine. As described below, Covetrus NA has implemented significant compliance measures designed to prevent these kinds of violations from recurring.

In this case, as in others, the Government has emphasized that the FDCA's restrictions on the distribution of veterinary prescription drugs are designed in part to protect humans from unsafe drug residue in the edible tissues of animals sold for slaughter. ECF No. 1 ¶ 6. By regulating the shipment of veterinary drugs, the FDCA reduces the likelihood that drugs will be administered to animals in excess of the approved dose, or in contravention of the appropriate withdrawal window, or used in another inappropriate manner that might contribute to the contamination problems that the Government has identified. While some of the shipments at issue in this case potentially implicate such concerns, Covetrus NA's business model was and is *not* primarily focused on animals in the human food supply chain. Covetrus NA's business poses a comparably small risk to human health because Covetrus NA's sales are only a small percentage of those made to veterinarians treating large animals. Accordingly, a one-year period of probation is appropriate and proportional to the lesser risk that Covetrus NA poses to the human food supply.

II. Covetrus NA's Existing Compliance Commitments Afford Adequate Deterrence and Protect the Public.

As part of the Plea Agreement, Covetrus NA has entered into a four-year Corporate Compliance Agreement. Even before making these formal commitments with the Government, Covetrus NA worked to revamp its business operations to give the Company the tools to make it capable of compliance with the FDCA. These changes will significantly lessen the chances of

future FDCA violations and protect the public from the public health concerns expressed by the Government. A summary of Covetrus NA's most significant compliance efforts is presented below.

In March 2021, approximately two years before the Government filed the Information in this case related to Covetrus NA's wholesale distributors, Covetrus NA initiated its Large Animal Pharmacy ("LAP"), which is designed to ship veterinary medicine on the order of veterinarians of all stripes (whether large animal vets or otherwise). Because it is a pharmacy licensed in the respective states to which it ships, it is able to fulfill veterinary drug orders at locations where distributors cannot ship. As of July 2023, the LAP is active in 49 states.

In 2021, Tamika Simmons joined Covetrus, Inc. as the Vice President of Global Regulatory Affairs and in 2023 was elevated to Chief Regulatory and Compliance Officer. Prior to joining Covetrus, Ms. Simmons spent almost fifteen years in legal and compliance roles in the human health industry. As Compliance Officer to both Covetrus North America and its parent company, Covetrus, Inc., Ms. Simmons develops policies, procedures and practices designed to address compliance with federal and state statutes and/or regulations concerning federal prescription drug distribution and FDA requirements. Ms. Simmons will also draft for review reports that include, but are not limited to, FDA and FDCA compliance obligations, including reports to the President of Covetrus North America, LLC; Ben Wolin, CEO of Covetrus, Inc.; and the Audit Committee of the Board of CVET Topco GP, LLC ("CVET Topco"). Ms. Simmons will also continue to report directly to the General Counsel of Covetrus, Inc.

In addition, the Covetrus NA Compliance Team works closely with the twenty-four members of the Company's Regulatory Affairs Team, which includes Kelly Ann Barnes, a registered pharmacist and attorney who serves as Senior Director of Regulatory Affairs; eleven

Controlled Substance Oversight and Order Fulfillment staff; three Controlled Substance Diversion Surveillance Program staff; and three Customer Onboarding and Licensure staff.

Under the leadership of Ms. Simmons, Covetrus NA has undertaken numerous compliance projects to reduce the risk of future FDCA violations. Prior to entering into the Plea Agreement, Covetrus NA completed a comprehensive, 50-state review of current state wholesale distribution regulations. As part of this review, Covetrus NA contacted the Chief Legal or Compliance Officers at the various state Boards of Pharmacy to inquire about their wholesale distribution regulatory requirements. Covetrus NA has used the information obtained in this 50-state review to update its internal veterinary distribution procedures and to develop rules designed to prevent veterinary drugs from being shipped to unauthorized locations. The shipment rules and procedures derived in part from this effort are currently in effect and are helping Covetrus NA meet its FDCA obligations right now. To bolster the efficacy of its procedures, Covetrus NA is implementing an operating system that will integrate Covetrus NA's shipment rules into the Company's ordering system, flagging shipments that would violate state regulations.

To facilitate the lawful shipment of veterinary medicine, and to reduce the potential for human error, Covetrus NA has engaged the services of several third-party applications that are integral to its compliance apparatus. Chief among these are Quorum and MedPro Systems. Quorum is a public affairs software provider that, among other things, allows Covetrus Regulatory Affairs personnel to keep track of state regulatory developments, including regulations that would impact the shipment of veterinary medicine. MedPro Systems aggregates and updates veterinary licensure data. MedPro licensure information has been integrated into Covetrus NA's enterprise resource planning software, meaning that this information is cross-referenced every time Covetrus NA ships veterinary prescription drugs.

Covetrus NA takes its compliance commitments seriously and, as demonstrated above, has expended substantial resources to preventing the offense conduct from recurring. In light of these commitments, Covetrus NA submits that a one-year term of probation is sufficient, but no greater than necessary, to deter future misconduct and protect the public.

III. A One-Year Term of Probation is Warranted in Light of Probationary Periods Imposed in Other Similar Cases.

A one-year term of probation is also appropriate in this case to avoid unwarranted sentencing disparities. This case is one of three similar cases that have been presented to this Court. *See United States v. Animal Health International, Inc. ("AHI")*, Crim. No. 1:20-cr-00007-JPJ-PMS and *United States v. Midwest Veterinary Supply, Inc.*, Crim. No. 1:23-MJ-00044-PMS. The veterinary drug distributors in those cases both pled guilty to similar offense conduct, entered into similar Compliance Agreements, and made similar programmatic changes to prevent future FDCA violations. The Defendant in *AHI* arguably engaged in more serious, far-reaching violations than the offense conduct at issue here— including, in that case, that the defendant distributed drugs to two fraudsters who distributed veterinary drugs without any appropriate licenses, one of whom operated out of a storefront called "Goin' Postal." *See* Information, *United States v. Animal Health International*, ECF No. 3 ¶¶ 6-11. In *AHI*, as in *Midwest*, the Court imposed a one-year term of probation. In light of the one-year terms imposed in those cases, a one-year term of probation is appropriate in this case.

Dated: April 8, 2024

/s/ W. Warren Hamel
W. Warren Hamel*
Anthony J. Vitti, Jr.*
VENABLE LLP
750 E. Pratt St.
Suite 900

Baltimore, MD 21202
(410) 244-7400 (T)
(410) 244-7742 (F)
whamel@venable.com
ajvitti@venable.com

and

Michael W. Robinson
VENABLE LLP
1850 Towers Crescent Plaza
Suite 400
Tysons, VA 22182
(703) 760-1600 (T)
(703) 821-8949 (F)

Counsel for Defendant Covetrus North America, LLC
**admitted pro hac vice*

CERTIFICATE OF SERVICE

I hereby certify that on this 8th day of April, 2024, I electronically filed the foregoing with the clerk of the court using the CM/ECF system, which will send notification of such filing to counsel:

Steven Randall Ramseyer
United States Attorney's Office – Abingdon
180 West Main Street, Suite B19
Abingdon, VA 24210
276-628-4161
Fax: 276-628-7399
Email: USAVAW.ECFAbingdon@usdoj.gov

/s/ W. Warren Hamel
W. Warren Hamel